Adverse Reactions

Technical specification for Supplier to NHS Digital delimited extract

Current version: v0.3 draft

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Contents

[Document Management 3](#_Toc57282160)

[Revision History 3](#_Toc57282161)

[Reviewers / Key Stakeholders 3](#_Toc57282162)

[Document Author 4](#_Toc57282163)

[Approved by 4](#_Toc57282164)

[1. Purpose of Document 6](#_Toc57282165)

[2. Introduction 6](#_Toc57282166)

[3. Data File Format 6](#_Toc57282167)

[3.1 Filename Format 6](#_Toc57282168)

[3.2 File Header 7](#_Toc57282169)

[3.3 File Footer 7](#_Toc57282170)

[3.4 Field Delimiter 8](#_Toc57282171)

[3.5 Record Delimiter 8](#_Toc57282172)

[3.6 Character values 8](#_Toc57282173)

[3.7 Date Time Formats 8](#_Toc57282174)

[3.8 Other considerations 8](#_Toc57282175)

[4. Data File Definition 9](#_Toc57282176)

[4.1 Adverse Reaction Data Items 9](#_Toc57282177)

[Appendix A 13](#_Toc57282178)

# Document Management

## Revision History

|  |  |  |
| --- | --- | --- |
| Version | Date | Summary of Changes |
| 0.1 | 11Nov20 | Initial draft, initial review comments captured |
| 0.2 | 18Nov20 | Subsequent draft, further internal NHS Digital & external Supplier & MHRA review comments captured and impacted |
| 0.3 | 19Nov20 | Final draft content post review conducted with all stakeholders at meeting on 18-Nov-2020 where all changes have been agreed. |
|  |  |  |

## Reviewers / Key Stakeholders

This document has been/must be reviewed by the following people – key Stakeholders highlighted

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| Clinical Advisory Group N/A - TDA sign-off of these low level specs is sufficient per Helen Galloway & Sebastian Tallents PA Consulting |  | CAG Signatory Title TBC | N/A  | v0.3  |
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| Helen Harger |  | Clinical Advisor, NHS Digital | 20/11/2020 | V0.3 |
| Gaynor Dalton (via Trevor Anders) |  | IG Lead |  |  |

# Purpose of Document

This document defines a file extract specification for provision of adverse reaction information relating to vaccinations, e.g. initially Coronavirus vaccination, to NHS Digital.

The intention is that this specification is healthcare setting agnostic, so can be used to support flow of information relating to vaccination related adverse reaction activity across Community Pharmacy, GP, Health and Justice (MOJ) healthcare settings and Coronavirus mass vaccination sites & mobile hubs for example.

Each of the data items required is detailed together with details on how the data should be formatted.

The document is intended to be used by both:

1. Developers in organizations supplying adverse reaction information to NHS Digital, as part of the extract creation process
2. Developers in NHS Digital, as input into the downstream design of the ingestion process, once the extract has landed within the NHS Digital boundary

Any changes or enhancements to the specification is subject to Change Control.

Design considerations as to file transfer mechanism (e.g. MESH) are not in scope of this document.

# Introduction

The scope of this document is to capture adverse reactions which occur within the first fifteen minutes after administration of the vaccination. From a clinical perspective the most common reactions expected within the first fifteen minutes are pain, bleeding at the injection site, erythema or urticaria.  Anaphylaxis may occur in rare cases. It is important to note that any of these reactions could occur beyond 15 minutes, and patients must be counselled to seek advice from an appropriate clinical source should they occur.  Capturing the data is reliant on:

* Citizen cooperation
* Availability of appropriate monitoring facilities
* Appropriately trained staff

# Data File Format

This section defines the required format of the file extract that organizations (System Suppliers) will provide to NHS Digital

## Filename Format

The filenames of the exported data files **must** be formatted by concatenating the following together with the underscore character as the delimiter:

* The data file type fixed as “AdverseReactions”
* The major and minor specification version of the file
* The sending organisation code as agreed with NHS Digital
* The timestamp of the export in format YYYYMMDDThhmmsszz
	+ YYYY = Year
	+ MM = Month (01-12)
	+ DD = Date (01-31)
	+ T = fixed value of “T”
	+ hh = Hours (00-23)
	+ mm = Minutes (00-59)
	+ ss = Seconds (00-59)
	+ time zone offset = 00 for GMT, 01 for BST

The file extension will be “.csv”

For example:

The filenaming convention of this technical specification v1.0 (approved) version of this document, containing adverse reaction data:

AdverseReactions\_v1\_0\_ABC123\_20201214T10081501.csv

A future hypothetical minor version update to this technical specification, e.g. v1.1 (approved) would be named e.g. as follows:

AdverseReactions\_v1\_1\_ABC123\_20201214T10081501.csv

A future hypothetical major version update to this technical specification, e.g. v2.0 (approved) would be named e.g. as follows:

AdverseReactions\_v2\_0\_ABC123\_20201214T10081501.csv

## File Header

Each data file **must** contain a header row containing the field names delimited by a pipe character. The field names must be the same as those specified in the next section.

For example:

NHS\_NUMBER|PERSON\_FORENAME|PERSON\_SURNAME|PERSON\_DOB|PERSON\_GENDER\_CODE|PERSON\_POSTCODE|CAUSATIVE\_AGENT\_CODING\_SYSTEM|CAUSATIVE\_AGENT\_CODING\_CODE|CAUSATIVE\_AGENT\_CODING\_DISPLAY|REACTION\_CODING\_SYSTEM|REACTION\_CODING\_CODE|REACTION\_CODING\_DISPLAY|REACTION\_DESCRIPTION|TYPE\_OF\_REACTION|REACTION\_SEVERITY|VERIFICATION\_STATUS|EVIDENCE|ONSET|UNIQUE\_ID|UNIQUE\_ID\_URI|ACTION\_FLAG|VACCINATION\_UNIQUE\_ID|VACCINATION\_UNIQUE\_ID\_URI|RECORDED\_DATE|NHS\_NUMBER\_STATUS\_INDICATOR\_CODE|NHS\_NUMBER\_STATUS\_INDICATOR\_DESCRIPTION|LOCAL\_PATIENT\_ID|LOCAL\_PATIENT\_URI

## File Footer

A file footer must **not** be submitted

## Field Delimiter

Each field in the data files **must** be enclosed within double quotes and delimited by a pipe character “|”. Pipe characters cannot appear within a data field.

Where this is no value (null) present, this will be represented as two consecutive delimiter characters (i.e. with no space character used), e.g. in the following, fields 2 and 8 have missing (null) values:

“The”||”Brown”|”Fox”|”Jumped”|”Over”|”The”||”Dog”

## Record Delimiter

Each record (i.e. row) in the data files **must** be terminated by the CR and LF characters.

## Character values

**String values**

Strings should contain printable alphanumeric characters only

**Escape characters**

All double quote characters within the data MUST be escaped with the backslash “\” character

## Date Time Formats

To avoid misunderstanding, where date time fields are used within the file, the following format should be used (characters such as : + - should not be included)

YYYYMMDDThhmmsszz

* The to values to be used are as follows:
	+ YYYY = Year
	+ MM = Month (01-12)
	+ DD = Date (01-31)
	+ T = fixed value of “T”
	+ hh = Hours (00-23)
	+ mm = Minutes (00-59)
	+ ss = Seconds (00-59)
	+ time zone offset = 00 for GMT, 01 for BST

## Other considerations

Where a patient has more than one adverse reaction, a record for each adverse reaction must be included. E.g. a patient having a Covid vaccination and experiencing anaphylaxis and erythema, because of the vaccine product, would result in two adverse reaction records being included in this file.

# Data File Definition

Mandatory (M) – field **must** be populated

Required (R) – field **must** be populated, but **only where data is available** and **guidance notes below instruct it**

Optional (O) – Supplier may choose to include this, where data is available

## Adverse Reaction Data Items

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Pos | Field Name | Data Type | Length / format / values | M/R/O | Notes |
| 1 | NHS\_NUMBER | String | 10 | R | **Every effort should be made to populate this, where possible**.Will be used to uniquely identify the patient. **When supplied will be validated immediately prior to submission.** Should be supplied without any padding spaces. |
| 2 | PERSON\_FORENAME | String |  | M | Patient Forename as registered on PDS. This will be one name only. This is needed for clinical safety.This field must be populated. |
| 3 | PERSON\_SURNAME | String |  | M | Patient Surname as registered on PDS. This is needed for clinical safety.This field must be populated. |
| 4 | PERSON\_DOB | Date | YYYYMMDD | M | Patient date of birth. This is needed for clinical safety. This field must be populated. |
| 5 | PERSON\_GENDER\_CODE | String | Use national codes from  https://datadictionary.nhs.uk/attributes/person\_gender\_code.html Use one of the following: 0     Not Known 1     Male 2     Female 9     Not Specified | M | Patient administrative gender. This field must be populated.  |
| 6 | PERSON\_POSTCODE | String | Up to 8As well as actual post codes, the following are to be used in other scenariosZZ99 3VZ No Fixed AbodeZZ99 3VZ Address Not KnownZ99 3CZ Address not specifiedV81999 (registered GP Practice Code not known)V81998 (registered GP Practice code not applicable)V81997 (No registered GP Practice)The full list is currently available here (see pages 8 & 103):https://www.england.nhs.uk/wp-content/uploads/2015/12/commissioner-assignment-process-flowchart-annotations.pdf | M | Patient postcode. Value should be divided into two parts (inward & outward) separated by a single space, e.g. EC1A 1BBThis field must be populated. |
| 7 | CAUSATIVE\_AGENT\_CODING\_SYSTEM | String | http://snomed.info/sct | M | Coding system (must be SNOMED SCT) used to record the causative agent |
| 8 | CAUSATIVE\_AGENT\_CODING\_CODE | String | AMP example:39114911000001105VMP example:39115611000001103 | M | Code used to record the Reaction.e.g. dm+d (SNOMED) Concept ID AMP (in preference) or VMP code for the vaccine product that caused the adverse reaction.  AMPP codes are also acceptable and are preferred over VMPP codes.See Appendix |
| 9 | CAUSATIVE\_AGENT\_CODING\_DISPLAY | String | AMP example:“Talent 0.5ml dose solution for injection multidose vials (Secretary of State for Health)”VMP example:“Generic Courageous 30micrograms/0.3ml dose concentrate for suspension for injection multidose vials” | R | Display value of the causative agent of the Reactione.g. dm+d (SNOMED) Concept ID AMP (in preference) or VMP term for the vaccine product that caused the adverse reaction.  AMPP terms are also acceptable and are preferred over VMPP terms. See Appendix |
| 10 | REACTION\_CODING\_SYSTEM | String | e.g. <http://snomed.info/sct> | M | Coding system used to record the reaction, must be a SNOMED SCTSee Appendix |
| 11 | REACTION\_CODING\_CODE | String | e.g. 247441003 | M | Code used to record the reaction, must be a SNOMED Concept ID code.See Appendix |
| 12 | REACTION\_CODING\_DISPLAY | String | e.g. Erythema (finding) | R | Display value of the causative agent of the reaction, must be a SNOMED Concept ID termSee Appendix |
| 13 | REACTION\_DESCRIPTION | String(max 6000) | e.g. “Erythema, papules, itching, blotches- all over the patient’s body \*please review” | R | Freetext description of reaction |
| 14 | TYPE\_OF\_REACTION | String | allergy, intolerance | O | Underlying mechanism of the reaction (if known). Value from <http://hl7.org/fhir/stu3/valueset-allergy-intolerance-type.html>See Appendix |
| 15 | REACTION\_SEVERITY | String | mild, moderate, severe | O | Clinical assessment of the severity of a reaction event as a whole. Code value from <http://hl7.org/fhir/stu3/valueset-reaction-event-severity.html> |
| 16 | VERIFICATION\_STATUS | String | unconfirmed, confirmed | M | Assertion about certainty associated with a propensity, or potential risk, of a reaction to the identified substance. Value from <http://hl7.org/fhir/stu3/valueset-allergy-verification-status.html>Only use confirmed in circumstance XYZ, otherwise use unconfirmed |
| 17 | EVIDENCE | String(max 200) | e.g. Hypersensitivity test confirmed | O | Freetext description of evidence |
| 18 | ONSET | Date time | YYYYMMDDThhmmsszz | M | Date(/time) when manifestations showed. (Date/time first experienced.) |
| 19 | UNIQUE\_ID | String | e.g.1) UUID example:33a62000-fc92-4ad9-afc1-02b65f65367e2) Example of a “single instance for all customers” Supplier systemACME-adversereaction1234563) Example of “per customer instance” Supplier systemACME-CUSTOMER1-adversereaction123456ACME-CUSTOMER2-adversereaction123456 | M | A unique identifier for the adverse reaction record, that is consistent between any subsequent update or delete records.Ideally this would be a GUID / UUIDValue in combination with UNIQUE\_ID\_URI must be globally unique |
| 20 | UNIQUE\_ID\_URI | String | e.g. 1) Example of a “single instance for all customers” Supplier system<https://supplierABC/identifiers>/adversereaction2) Example of “per customer instance” Supplier systemhttps://supplierABC/ODSCode\_ NKO41/identifiers/adversereaction | M | A URI for the system that has allocated the adverse reaction identifier.Note, this must be unique within a given Supplier system or instance of Supplier system |
| 21 | ACTION\_FLAG | String | new / update / delete | M | Indication if the record is new, or has been re-submitted following an update or delete to one previously provided |
| 22 | VACCINATION\_UNIQUE\_ID | String | e.g.1) UUID example:e045626e-4dc5-4df3-bc35-da25263f901e2) Example of a “single instance for all customers” Supplier systemACME-vacc1234563) Example of “per customer instance” Supplier systemACME-CUSTOMER1-vacc123456ACME-CUSTOMER2-vacc123456 | M | A unique identifier for the (causative) vaccination record the adverse reaction relates to.Ideally this would be a GUID / UUIDValue in combination with VACCINATION\_UNIQUE\_ID\_URI value must be globally unique. In other words, a combination of VACCINATION\_UNIQUE\_ID and VACCINATION\_UNIQUE\_ID\_URI act as composite foreign key to allow lookup of further information from the corresponding vaccination record vaccination data file. |
| 23 | VACCINATION\_UNIQUE\_ID\_URI | String | e.g. 1) Example of a “single instance for all customers” Supplier system<https://supplierABC/identifiers>/vacc2) Example of “per customer instance” Supplier systemhttps://supplierABC/ODSCode\_ NKO41/identifiers/vacc | M | A URI for the system that has allocated the vaccination identifier.Note, this must be unique within a given Supplier system or instance of Supplier system |
| 24 | RECORDED\_DATE | Date | YYYYMMDD | R |  |
| 25 | NHS\_NUMBER\_STATUS\_INDICATOR\_CODE | String | Code value from <https://datadictionary.nhs.uk/attributes/nhs_number_status_indicator_code.html?hl=trace> | M | The trace status code of the [NHS\_NUMBER](https://datadictionary.nhs.uk/attributes/nhs_number.html) (where provided) |
| 26 | NHS\_NUMBER\_STATUS\_INDICATOR\_DESCRIPTION | String | Description value from <https://datadictionary.nhs.uk/attributes/nhs_number_status_indicator_code.html?hl=trace> | R | The trace status description of the [NHS\_NUMBER](https://datadictionary.nhs.uk/attributes/nhs_number.html) (where provided) |
| 27 | LOCAL\_PATIENT\_ID | String |  | M | Local patient identifier value for system providing the data. Where there is no local patient identifier, provide the NHS Number |
| 28 | LOCAL\_PATIENT\_URI | String | e.g.https://supplierABC/identifiers | M | A URI for the system that has allocated the local patient identifier |

# Appendix A

Example file



The following are suggested values for some of the various fields.

**Row 8 CAUSATIVE\_AGENT\_CODING\_CODE & 9 CAUSATIVE\_AGENT\_CODING\_DISPLAY**

AMP: 39115611000001103 Courageous 30micrograms/0.3ml dose concentrate for suspension for injection multidose vials (Secretary of State for Health)

AMP: 39114911000001105 Talent 0.5ml dose solution for injection multidose vials (Secretary of State for Health)

**ROW 10 REACTION\_CODING\_SYSTEM & Row 11 REACTION\_CODING\_CODE & 12 REACTION\_CODING\_DISPLAY**

*Note: In the FHIR profile for Digital Medication and Allergy Intolerance the Manifestation data item point to the SNOMED Clinical Hierarchy however, following further clinical consultation it has been deemed more appropriate to make use of the following Simple Reference set.*

*We are going to follow the appropriate governance process to recommend the necessary changes to the FHIR profile.*

We are only accepting codes from the Health issues simple reference set

Refset Id : 1127601000000107

Any value for this reference set is acceptable however the list included in the specification is those things that a group of medical professionals believe are most likely in the first 15 minutes after receiving an intramuscular injection.

SCTID: 95388000 Injection site pain (disorder)

SCTID: 860897009 Injection site erythema (disorder)

SCTID: 846686009 Injection site itching (finding)

SCTID: 131148009 Bleeding (finding)

SCTID: 95394008 Injection site urticaria (disorder)

SCTID: 15920121000119103 Allergic reaction caused by vaccine product (disorder)

SCTID: 417516000 Anaphylaxis caused by substance (disorder)

SCTID: 863910007 Vaccination site swelling (disorder)

SCTID: 863894003 Injection site pruritus (disorder)

SCTID: 422400008 Vomiting (disorder)

SCTID: 4386001 bronchospasm (finding)

SCTID: 247441003 Erythema (finding)

SCTID: 91175000 Seizure (finding)

SCTID: 271594007 Syncope (disorder)

SCTID: 404640003 Dizziness (finding)

SCTID: 25064002 Headache (finding)

SCTID: 422587007 Nausea (finding)

SCTID: 421262002 Tongue swelling (finding)

SCTID: 699376002 Lip swelling (finding)

SCTID: 278528006 Facial swelling (finding)

SCTID: 247472004 Weal (disorder)

**Row 14 TYPE\_OF\_REACTION**

allergy - A propensity for hypersensitivity reaction(s) to a substance. These reactions are most typically type I hypersensitivity, plus other "allergy-like" reactions, including pseudoallergy.

intolerance - A propensity for adverse reactions to a substance that is not judged to be allergic or "allergy-like". These reactions are typically (but not necessarily) non-immune. They are to some degree idiosyncratic and/or individually specific (i.e. are not a reaction that is expected to occur with most or all patients given similar circumstances).